U.S.S.N.:

Applicant: Nakagawa e 09/051,670

Filed:

September 8, 1998

Page 4

# **BASIS FOR AMENDMENTS**

Claims 1, 2, and 6 have been amended to clarify that the claimed DNA molecule has a nucleotide sequence that has one segment that corresponds to SEQ ID NO:1 and another segment that corresponds to SEQ ID NO:2. Support for this amendment is found in the specification at page 14, line 1, through page 15, line 19, wherein Applicants teach a DNA molecule that has at least one segment that corresponds to SEQ ID NO:1 and another segment that corresponds to SEQ ID NO:2.

Claim 2 has been further amended to place the claim into proper form by removing surplus language, while requiring that the claimed DNA molecule encode a protein that inhibits differentiation or maturation of osteoclasts. This amendment is supported in the specification in SEQ ID NOS: 1 and 2, and at page 4, lines 4-6.

New claims 7-12 have been added in order to clarify that the claimed DNA molecule of base claims 1, 2, and 6 does not require a specific order to the first and second segments. Support for this amendment is found in the specification at page 14, line 1, through page 15, line 19, wherein Applicants recite a DNA molecule that has at least one segment that corresponds to SEQ ID NO:1, and another segment that corresponds to SEQ ID NO:2, but do not teach that the segments must be in any specific order.

No new matter has been introduced by these amendments.

## REMARKS

Claims 1, 2, 5, and 6 are pending in this application. In the Office Action mailed on December 6, 1999, the Examiner objected to claims 1, 2, and 6 as failing to comply with 37 C.F.R. § 1.822(e), and rejected claims 1, 2, and 6 under 35 U.S.C. § 112, second paragraph. The Examiner stated that claim 5 was allowable.

Applicant: Nakagawa et U.S.S.N.:

09/051,670

Filed:

September 8, 1998

Page 5

#### 1. The Objection

Claims 1, 2, and 6 were objected to as failing to comply with 37 C.F.R. § 1.822(e). Applicants respectfully note that the quotation in the Office Action that was attributed to section (e) of Rule 822 is actually from section (o), and accordingly address this objection as being under section (o). Specifically, the Examiner indicated that Rule 822(o) requires that the claimed DNA molecule be presented as a separate sequence, quoting the second sentence of Rule 822(o). Rule 822 (o) states in full:

A sequence with a gap or gaps shall be presented as a plurality of separate sequences, with separate sequence identifiers, with the number of separate sequences being equal in number to the number of continuous strings of sequence data. A sequence that is made up of one or more noncontiguous segments of a larger sequence or segments from different sequences shall be presented as a separate sequence. (Emphasis added).

The related M.P.E.P section, § 2423.03, states that "[t]he 'gaps' referred to in this section are gaps representing unknown or undisclosed regions in a sequence between regions that are known or disclosed." Applicants respectfully submit that it is the first sentence, and not the second sentence, of Rule 822(o) that applies to the DNA molecule recited by claims 1, 2, and 6. The DNA molecule recited by claims 1, 2, and 6 is made up, in part, of two complete sequences (as represented by SEQ ID NOS: 1 and 2), and may contain gaps of unknown or undisclosed regions. The DNA molecule recited by Applicants' claims is not made up of noncontiguous segments of a larger sequence or from different sequences. As such, the DNA molecule recited by Applicants' claims is properly presented by a number of different sequences, and should not be presented as a separate sequence.

In order to clarify this distinction, Applicants have amended claims 1, 2 and claim 6 to recite a first and a second segment, the segments having a nucleotide sequence corresponding to SEQ ID NOS: 1 and 2, respectively. Accordingly, Applicants

Applicant: Nakagawa et 09/051,670

Filed:

September 8, 1998

Page 6

respectfully request that the objection to claims 1, 2, and 6 be reconsidered and withdrawn.

#### 2. The Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1, 2, and 6 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Specifically, the Examiner stated that claim 2 was indefinite because it recited a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation. Applicants have amended claim 2 to clarify the limitation with respect to the recitation of the sequences.

In addition, the Examiner stated that claims 1, 2, and 6 were indefinite because the order in the DNA molecule of SEQ ID NOS: 1 and 2 was not clearly set forth. Applicants respectfully submit that the claim language "comprising at least a first and a second segment" is definite in that the claimed DNA molecule must contain those recited segments, regardless of the order in which the segments appear. Applicants further respectfully submit that the specification does not teach that any particular order is required by their invention. As such, Applicants believe that they need not limit their claimed DNA molecule with respect to the order of the segments. Nevertheless, in order to emphasize that base claims 1, 2, and 6 do not require a specific order to the segments, Applicants have added new claims 7-12, which claim alternate arrangements of the segments in the claimed DNA molecule.

Applicants respectfully submit that all of the Examiner's concerns under 35 U.S.C. § 112, second paragraph, have been addressed. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

Applicant: Nakagawa e U.S.S.N.: 09/051,670

Filed:

September 8, 1998

Page 7

### **Conclusion**

Applicants respectfully submit that the claims are now in condition for allowance. If the Examiner believes that a conversation with Applicants' attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at the telephone number below.

Respectfully submitted,

Date:

Reg. No. 43,526

Tel. No. (617) 248-7476

Fax: (617) 248-7100

Jennifer A. Camacho

Attorney for the Applicants

Testa, Hurwitz, & Thibeault, LLP

High Street Tower 125 High Street

Boston, Massachusetts 02110

479JAC3999/66.949385-1